TENT COOPERATION TRE Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 June 1999 (03.06.99)	
International application No. PCT/GB98/03073	**Applicant's or agent's file reference** LPB/P15367WO
International filing date (day/month/year) 12 October 1998 (12.10.98)	**Priority date** (day/month/year) 10 October 1997 (10.10.97)
Applicant DOUGAL, Gordon, Rex, Paterson	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

09 April 1999 (09.04.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer S. Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

24.JAN.2000*023642

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

To:

Harrison Goddard Foote
Belmont House
20 Wood Lane
Leeds LS6 2AE
GRANDE BRETAGNE

Date of mailing *(day/month/year)* 21. 01. 00

Applicant's or agent's file reference
LPB/P15367WO

IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/03073	12/10/1998	10/10/1997

Applicant
VIRULITE LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer
Ulrich, C

Tel.+49 89 2399-2322

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
LPB/P15367WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/03073	12/10/1998	10/10/1997
International Patent Classification (IPC) or national classification and IPC A61N5/06		
Applicant VIRULITE LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
VI	☐	Certain documents cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09/04/1999	21.01.00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schoeffmann, H Telephone No. +49 89 2399 2625

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB98/03073

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1,3-5,8-21	as originally filed			
2,6,7	as received on	16/09/1999	with letter of	09/09/1999

Claims, No.:

1-30	as received on	16/09/1999	with letter of	09/09/1999

Drawings, sheets:

1/9-9/9	as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 27-30.

because:

☒ the said international application, or the said claims Nos. 27-30 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	in combination: 1,4,24,25 or 1,4,26
	No:	Claims	2,3,5-23
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

ad III:

1. For the assessment of present claims 27-30 on the question whether it is industrially applicable, no unified criteria exist in the PCT. The IPEA therefore is not required to carry out an examination on these claims (Cf. Rule 67.1(iv) PCT).

   The patentability may be dependent upon the formulation of the claim. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

   The above claims pertain to a method of treatment by irradiation of a patient with infrared light. Such methods might not be regarded as an invention susceptible of industrial application.

ad V:

1. Reference is made to the following documents:

   D1... US-A-5 445 146
   D2... US-A-5 259 380
   D3....EP-A-0 416 150 (copy enclosed)

2. Document D3 discloses an electromagnetic therapy system comprising

   - means (fig.1, (2)) for emitting divergent electromagnetic radiation between 980 and 1500 nm (cf. abstract) and being capable of producing, at the site being treated, a radiation intensity of at least 50uW/cm^2 and up to 2W/cm^2 (cf. page 1, lines 3-6).

   The distance between focussing lens and diode is adjustable such that focus is placed within the housing (cf. page 4, lines 32-35). In that case only divergent radiation is emitted.
   Moreover, it is evident that even when the focus lies within the aperture that, depending on distance from the aperture, any of the claimed radiation intensities

THIS PAGE BLANK (USPTO)

may be produced at the site being treated.

Therefore, the subject-matter of claim 1 thus lacks novelty so that the requirement of Art.33(2) PCT is not met.

3. The features as defined in the dependent claims 2,3,5,6-23 appear conventional in the context. Since they have been applied before substantially for the same purpose, their inclusion in a device as known from D3 is considered obvious for the one skilled in the art. No combination of claims thus provides for inventive subject-matter (Art.33(3) PCT):

claim 2: 600-1100 nm have been disclosed in D3 so that there is an overlap with the claimed range of 980-1300; see also D1, col.3, lines 45-60;

claim 3: 1064nm as of a Nd:YAG laser (cf. D1) is about 1072 nm;

claim 5: a half divergence angle in the range between 17 and 45 degrees is obvious and will be selected according to circumstances once it is known to provide divergent radiation; see also D3, fig.1;

claims 6-15,20: continuous or pulsed radiation, see D1, col.3, lines 57-60 and col.4, lines 2-5; or D3, page 4, lines 45-50;

claims 16,17: means for reducing ambient light, see D2, fig.2, LEDs mounted on a sphere which, when pressed against the patient's skin, will prevent stray light from impinging on the site of treatment; also D3, fig.1;

claim 18: means for fixing the intensity within a predetermined range, see D1, col.4, lines 47-54 and lines 55-66;

claim 19: a display for indicating operation of diodes emitting invisible light appears compulsory in order to make clear to the user that the device is operating;

claims 21,22: LEDs, see D2, fig.2, (12);

claim 23: glass fiber for delivery of the radiation, see D1, col.4, lines 14-17;

4. The features as defined by a combination of claims 1, 4, 24 and 25 or 1,4 and 26 do not appear to be known from the cited prior art so that they might be considered to meet the requirements of Art.33(2)-(4) PCT, in particular, in that no prior art renders obvious the use of 1268 nm for electromagnetic therapy. Before however the inventive step of these claims can be acknowledged in general,

national patent offices might require comparative tests which give evidence of the effectiveness of the radiation. Such tests need to be carried out by an independent and generally acknowledged authority.

ad VII:

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (see document D3 and item V.2. above) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

ad VIII:

1. The application fails to indicate an example of a gas discharge light source generating 1072 or 1268 nm, as required by Rule 5.1 a) v) PCT.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* LPB/P15367WO

Box No. I TITLE OF INVENTION

Electromagnetic Radiation Therapy

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

Virulite Limited
PO Box 210
Darlington
DL3 9GZ
England

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(i.e. country)* of nationality: GB

State *(i.e. country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)*

DOUGAL, Gordon Rex Paterson
Hartlepool General Hospital
Holdforth Road
Hartlepool
TS24 9AH
ENGLAND

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(i.e. country)* of nationality: ZA

State *(i.e. country)* of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

HARRISON GODDARD FOOTE
Patent and Trade Mark Attorneys
Belmont House
20 Wood Lane
Leeds LS6 2AE
ENGLAND

Telephone No. +44 113 225 8350

Facsimile No. +44 113 230 4702

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a)*(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- ☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT*(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☒ AL Albania
- ☒ AM Armenia
- ☒ AT Austria
- ☒ AU Australia
- ☒ AZ Azerbaijan
- ☒ BA Bosnia and Herzegovina
- ☒ BB Barbados
- ☒ BG Bulgaria
- ☒ BR Brazil
- ☒ BY Belarus
- ☒ CA Canada
- ☒ CH and LI Switzerland and Liechtenstein
- ☒ CN China
- ☒ CU Cuba
- ☒ CZ Czech Republic
- ☒ DE Germany
- ☒ DK Denmark
- ☒ EE Estonia
- ☒ ES Spain
- ☒ FI Finland
- ☒ GB United Kingdom
- ☒ GE Georgia
- ☒ GH Ghana
- ☒ GM Gambia
- ☒ GW Guinea-Bissau
- ☒ HU Hungary
- ☒ ID Indonesia
- ☒ IL Israel
- ☒ IS Iceland
- ☒ JP Japan
- ☒ KE Kenya
- ☒ KG Kyrgyzstan
- ☒ KP Democratic People's Republic of Korea
- ☒ KR Republic of Korea
- ☒ KZ Kazakhstan
- ☒ LC Saint Lucia
- ☒ LK Sri Lanka
- ☒ LR Liberia
- ☒ LS Lesotho
- ☒ LT Lithuania
- ☒ LU Luxembourg
- ☒ LV Latvia
- ☒ MD Republic of Moldova
- ☒ MG Madagascar
- ☒ MK The former Yugoslav Republic of Macedonia
- ☒ MN Mongolia
- ☒ MW Malawi
- ☒ MX Mexico
- ☒ NO Norway
- ☒ NZ New Zealand
- ☒ PL Poland
- ☒ PT Portugal
- ☒ RO Romania
- ☒ RU Russian Federation
- ☒ SD Sudan
- ☒ SE Sweden
- ☒ SG Singapore
- ☒ SI Slovenia
- ☒ SK Slovakia
- ☒ SL Sierra Leone
- ☒ TJ Tajikistan
- ☒ TM Turkmenistan
- ☒ TR Turkey
- ☒ TT Trinidad and Tobago
- ☒ UA Ukraine
- ☒ UG Uganda
- ☒ US United States of America
- ☒ UZ Uzbekistan
- ☒ VN Viet Nam
- ☒ YU Yugoslavia
- ☒ ZW Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐ .....
- ☐ .....
- ☐ .....

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____.

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country *(in which, or for which, the application was filed)*	Filing Date *(day/month/year)*	Application No.	Office of filing *(only for regional or international application)*
item (1) GB	31 DEC 1997	9727441.9	
item (2) GB	10 OCT 1997	9721506.5	
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s) : _____

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA / _____

Earlier search *Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:*

Country (or regional Office): Date *(day/month/year)*: Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request	:	3	sheets
2. description	:	21	sheets
3. claims	:	4	sheets
4. abstract	:	1	sheets
5. drawings	:	11	sheets
Total	:	40	sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) *identified in Box No. VI as item(s):*
5. ☐ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☐ nucleotide and/or amino acid sequence listing (diskette)
8. ☐ other *(specify)*: Form 23/77 (x2)

Figure No. _____ of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Harrison Goddard Foote

Harrison Goddard Foote

For receiving Office use only

1. Date of actual receipt of the purported international application:	2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority specified by the applicant: ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
LPB/P15367WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 98/ 03073	12/10/1998	10/10/1997
Applicant		
VIRULITE LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:
   Figure No. 1
   - [ ] as suggested by the applicant.
   - [X] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/03073

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

with the herpes virus by treatment with light of the wavelength 660nm, as described in US 5500009. However, the present inventor was unable to achieve a significant clinical outcome or benefit at that wavelength.

Additionally, it is known from the prior art to use a laser to produce coherent radiation and to focus it on the area to be treated. Nd YAG laser treatment at a fundamental wavelength of 1064 nm is associated with decreased pain, scarring and improved healing (US 5445146). Additionally it has been reported that diodes emitting light at the red wavelength, 940 ± 25 nm can be used to treat a range of essentially musculoskeletal ailments (US 5259380). However there is no indication that light of a wavelength above this would be of any therapeutic use.

It has now been surprisingly established that low intensity electromagnetic radiation of small bandwidth is effective in the treatment of infectious diseases, inflammatory-type diseases and other conditions, including the alleviation of pain. It is postulated that the way in which the electromagnetic radiation effects its action is by way of energy transmission through cellular components/organelles.

A water molecule that has a range of electromagnetic radiation wavelengths passed through it will produce several transmission peaks. These transmission peaks are associated with the preferred therapeutic electromagnetic radiation wavelength range of the invention and thus implies a role for the water molecule in the general mechanism of action.

Statements of the Invention

According to the present invention there is provided an electromagnetic radiation therapy system comprising means for emitting divergent electromagnetic radiation between 950 and 1500 nm and being capable of producing, at the site being treated, a radiation intensity of at least 50 μWatts/cm^2 .

In the case where the system is to be used in such a way that radiation will be caused to enter the eye, it is preferred that the power intensity does not exceed 100 mWatts/cm^2. Otherwise, the power intensity may be higher and can suitably be delivered in pulsed form, thereby obtaining several watts of momentary power output, allowing good penetration of tissue and substantial systemic effect.

The radiation producing means are preferably solid state light emitting devices, more preferably solid state light emitting diodes or gas discharge devices. The radiation from such devices can be electrically operated or the radiation can be delivered to an applicator via a fibre-optic delivery system.

Preferably, the radiation emitter includes a PN junction arranged to emit radiation with a wavelength centring at or about 1072nm or at or about 1268 nm. A single light diode assembly may include a plurality of orientated junctions.

Infrared emitting diodes may be arranged not only to emit radiation at a specific frequency but also to emit a high intensity divergent beam.

A gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072 nm.

Another preferred radiation producing means is a laser diode device, an example being a laser diode emitting light at a frequency of 1064.nm. Such a light emitting means is of low power intensity having a divergent beam and not giving rise to thermal damage. It may be used to treat many conditions, including pain relief.

The present invention also provides the use of divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm and an intensity of at least 50μWatts/cm^2 to treat an area of biological tissue of a living human or animal subject.

Preferably the electromagnetic radiation as produced by the system of the invention provides for treating conditions such as, without limitation, herpetic infections, bacterial and/or viral infections of the skin or upper respiratory tract, ophthalmic conditions such as "dry eye syndrome", caustic injuries, musculoskeletal conditions, inflammatory conditions such as rheumatoid arthritis and malignancies, reduction of scarring, promotion of wound healing, sports performance and providing acute and chronic pain relief.

The use of restricted bandwidth radiation can enhance the immune system as a result of which the body is able to combat infections, such as the herpes virus.

Although reference has been made to infections caused by the herpes virus, the present invention is not limited to such infections. It is applicable to other infections caused by all viruses including HIV, common cold and influenza viruses.

The present invention also provides a method of treating an area of biological tissue of a living human or animal subject comprising applying to said area divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm at an intensity of at least 50μWatts/cm^2.

Preferably, the area to be treated is irradiated so that the affected tissue receives at least 50-500 μWatts/cm^2 peak power of radiant energy, depending on the tissue to be treated. A factor here is the period of irradiation and, preferably, the period should be at least a specified minimum of 10-15 μseconds at a repetition rate /frequency of 450-800 Hz and preferably for at least 30 seconds duration.

Brief Description of the Drawings

Embodiments of the invention will now be described, by way of examples only, and with reference to the accompanying drawings, in which: -

CLAIMS

1. An electromagnetic radiation therapy system comprising means for emitting divergent electromagnetic radiation between 950 nm and 1500 nm and being capable of producing, at the site being treated, a radiation intensity of at least 50 μWatts/cm^2.

2. An electromagnetic radiation therapy system according to either of Claims 1 or 2 wherein the wavelength is in the range 980nm-1300nm.

3. An electromagnetic radiation therapy system according to any preceding claim wherein the wavelength is at, or about, 1072nm.

4. An electromagnetic radiation therapy system according to any preceding claim wherein the wavelength is at, or about, 1268nm.

5. An electromagnetic radiation therapy system according to any preceding claim wherein the half angle divergence of the electromagnetic radiation is in the range 15° to 45°.

6. An electromagnetic radiation therapy system according to any preceding claim wherein the electromagnetic radiation is continuous or pulsed.

7. An electromagnetic radiation therapy system according to any preceding claim wherein, in the instance of the electromagnetic radiation being continuous, the intensity is at least 50 μWatts/cm^2 for treatment of eyes and mucous membranes and up to 2 Watts/cm^2.

8. . An electromagnetic radiation therapy system according to any preceding claim wherein, in the instance of the electromagnetic radiation being continuous, the intensity is at least 500 μWatts/cm^2 for treatment of skin and up to 2 Watts/cm^2.

9. An electromagnetic radiation therapy system according to any of Claims 1-6, wherein in the instance of the electromagnetic radiation being pulsed, the intensity is at least 50 μWatts/cm^2 peak power for treatment of eyes and mucous membranes and the average power is up to 2 Watts/cm^2.

10. An electromagnetic radiation therapy system according to any of Claims 1-6, wherein in the instance of the electromagnetic radiation being pulsed, the intensity is at least 500 μWatts/cm^2 peak power for treatment of skin and the average power is up to 2 Watts/cm^2.

11. An electromagnetic radiation therapy system according to any of Claims 1-6 or 9 or 10 wherein the average power of the pulsed electromagnetic radiation intensity is in the region of 50-100μWatts/ cm^2.

12. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-11 wherein pulsed electromagnetic radiation is applied for periods of at least 10-15 μseconds.

13. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-12 wherein the pulsed electromagnetic radiation is applied at a frequency/repetition rate in the range 480-800 Hz.

14. An electromagnetic radiation therapy system according to Claim 13 wherein the frequency/repetition rate is at, or about, 600 Hz.

15. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-14 wherein the pulsed electromagnetic radiation is applied to the affected area for at least 30 seconds and up to 15 minutes.

16. An electromagnetic radiation therapy system according to any preceding claim wherein the electromagnetic radiation therapy system also includes means for

reducing the amount of ambient radiation which impinges on the site of treatment.

17. An electromagnetic radiation therapy system according to Claim 16 wherein the means for excluding ambient radiation excludes radiation below 400-500 nm.

18. An electromagnetic radiation therapy system according to any preceding claim further including means for fixing the intensity of the radiation within a pre-determined range.

19. An electromagnetic radiation therapy system according to any preceding claim wherein radiation output is monitored with a visible display indicating correct function of the device both for intensity and wavelength.

20. An electromagnetic radiation therapy system according to any preceding claim further including further including means for controlling the duration of the application of the radiation.

21. An electromagnetic radiation therapy system according to any preceding claim wherein the radiation producing means are solid state light emitting devices,

22. An electromagnetic radiation therapy system according to Claim 21 wherein the solid state light emitting devices are solid state light emitting diodes or gas discharge devices or a laser diode device.

23. An electromagnetic radiation therapy system according to either Claim 21 or 22 wherein radiation from such devices is electrically operated or delivered to an applicator via a fibre-optic delivery system.

24. An electromagnetic radiation therapy system according to any of Claims 21-23 wherein the radiation emitter includes a PN junction arranged to emit radiation with a wavelength centring at, or about, 1072nm or at, or about, 1268 nm.

25. An electromagnetic radiation therapy system according to Claims 24 wherein a single light diode assembly include a plurality of orientated junctions.

26. An electromagnetic radiation therapy system according to Claims 22 wherein the gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072 nm or 1268 nm.

27. The use of divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm and an intensity of at least 50μWatts/cm^2 to treat an area of biological tissue of a living human or animal subject.

28. The use according to Claim 27 for treating herpetic infections, bacterial and/or viral infections of the skin or upper respiratory tract, ophthalmic conditions such as "dry eye syndrome", caustic injuries, musculoskeletal conditions, inflammatory conditions such as rheumatoid arthritis and malignancies, reduction of scarring, promotion of wound healing, improving sports performance and providing acute and chronic pain relief.

29. The use of according to Claim 27 for treating the immune system as a result of which a human or animal subject is able to combat infections, such as the herpes virus.

30. A method of treating an area of biological tissue of a living human or animal subject comprising applying to said area divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm at an intensity of at least 50μWatts/cm^2.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/06

A1

(11) International Publication Number: WO 99/19024

(43) International Publication Date: 22 April 1999 (22.04.99)

(21) International Application Number: PCT/GB98/03073

(22) International Filing Date: 12 October 1998 (12.10.98)

(30) Priority Data:

9721506.5	10 October 1997 (10.10.97)	GB
9727441.9	31 December 1997 (31.12.97)	GB

(71) Applicant *(for all designated States except US)*: VIRULITE LIMITED [GB/GB]; P.O. Box 210, Darlington DL3 9GZ (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: DOUGAL, Gordon, Rex, Paterson [ZA/GB]; Hartlepool General Hospital, Holdforth Road, Hartlepool TS24 9AH (GB).

(74) Agent: HARRISON GODDARD FOOTE; Belmont House, 20 Wood Lane, Leeds LS6 2AE (GB).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

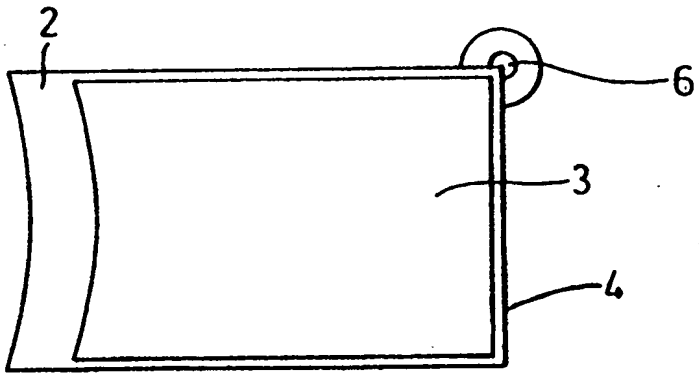
Published

With international search report.

(54) Title: ELECTROMAGNETIC RADIATION THERAPY

(57) Abstract

An electromagnetic radiation therapy system comprises means for emitting divergent electromagnetic radiation having a wavelength between 950 and 1500 nm and being capable of producing, at the site being treated, a radiation intensity of at least 50 μWatts/cm^2. Also disclosed are the use of the system for treating various conditions and the method of applying the treatment.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

ELECTROMAGNETIC RADIATION THERAPY

Field of the Invention

This invention relates to an apparatus producing, and a method of therapy using, electromagnetic radiation for the treatment of diseases and for the maintenance or improvement of organs or body tissues, including muscles. The invention may be used in connection with the cure or alleviation of a variety of diseases including infectious diseases and pathological processes including those caused by viruses and bacteria.

By way of example, the invention may be used in connection with diseases caused by the herpes virus which is known to be responsible for a number of common ailments including corneal dendritic ulcers, genital herpes, herpes labialis (cold sores), herpes zoster (shingles) and herpes stomatitis. These infections tend to be recurrent and are not cured by existing, medically accepted treatments.

Background of the Invention

Current medically accepted methods of treating infections caused by the herpes virus are chemotherapeutic agents which are applied topically, injected or taken orally. Such treatment can often deal with the immediate infection but does not prevent a recurrence of the infection at a later date after the treatment has ceased.

It has been known for several decades that the use of light can give a positive therapeutic effect in the treatment of a wide spectrum of diseases. In the 1960's the use of narrow wavelength light was investigated in *in vivo/in vitro* experiments. It was found that light of wavelength greater than 440nm did not work. Further investigations were carried out with light having a wavelength of from 300 to 350nm (UV light) but it was found that infection was exacerbated/promoted rather than ameliorated/eliminated. Some attempts have been made to treat individuals affected

with the herpes virus by treatment with light of the wavelength 660nm, as described in US 5500009. However, the present inventor was unable to achieve a significant clinical outcome or benefit at that wavelength.

Additionally, it is known from the prior art to use a laser to produce coherent radiation and to focus it on the area to be treated. Nd YAG laser treatment at a fundamental wavelength of 1064 nm is associated with decreased pain, scarring and improved healing (US 5445146). Additionally it has been reported that diodes emitting light at the red wavelength, 940 ± 25 nm can be used to treat a range of essentially musculoskeletal ailments (US 5259380). However there is no indication that light of a wavelength above this would be of any therapeutic use.

It has now been surprisingly established that low intensity electromagnetic radiation of small bandwidth is effective in the treatment of infectious diseases, inflammatory-type diseases and other conditions, including the alleviation of pain. It is postulated that the way in which the electromagnetic radiation effects its action is by way of energy transmission through cellular components/organelles.

A water molecule that has a range of electromagnetic radiation wavelengths passed through it will produce several transmission peaks. These transmission peaks are associated with the preferred therapeutic electromagnetic radiation wavelength range of the invention and thus implies a role for the water molecule in the general mechanism of action.

Statements of the Invention

According to the present invention there is provided an electromagnetic radiation therapy system comprising means for emitting divergent electromagnetic radiation between 950 and 1500 nm and being capable of producing, at the site being treated, a radiation intensity of at least 50 μWatts/cm^2.

Reference herein to a site being treated is intended to include, without limitation, the skin or musculature or internal organ of a human or animal subject.

Preferably the wavelength of the electromagnetic radiation is in the range 980nm-1300nm. A particularly preferred wavelength is at, or about, 1072nm. A yet further particularly preferred wavelength is at, or about, 1268nm.

Our studies have shown that the wavelength centred around 1072 nm is particularly effective at treating herpetic and bacterial infections, alleviating acute pain and in treating eye conditions, whilst the wavelength centred around 1268 nm is particularly effective at providing pain relief from deep muscle injury. It is of note that these two preferred wavelengths correspond to the peak emission wavelengths of a water molecule light transmission profile and thus we believe that the mechanism of action is related to water and possibly cell membranes.

By divergent it meant that the electromagnetic radiation emitted from the system of the invention has a divergent half angle of at least 5°. Preferably divergence of the electromagnetic radiation is in the range 15° to 45° half angled divergent.

Preferably the electromagnetic radiation is continuous or pulsed.

Preferably when the electromagnetic radiation is continuous the intensity is at least 50 μWatts/cm^2 for treatment of eyes and mucous membranes, and more preferably is at least 500 μWatts/cm^2 for treatment of skin and up to 2 Watts/cm^2.

Preferably when the electromagnetic radiation is pulsed the intensity is at least 50 μWatts/cm^2 peak power for treatment of eyes and mucous membranes, and more preferably is at least 500 μWatts/cm^2 peak power for treatment of skin and the average power is up to 2 Watts/cm^2. The average power is the peak power multiplied by the proportion of the total time that the radiation is applied. For instance if the

peak power is 500 μWatts/cm² and is pulsed for 10 μseconds at a frequency of 600 Hz then the average power is 30μ Watts/ cm².

Preferably when the electromagnetic radiation is pulsed the average power of the intensity is in the region of 50-100μ Watts/ cm².

We have found that the power may suitably range from 500 μWatts/cm² peak to 2 Watts/cm² continuous or peak power when applied to the skin. In the instance of applying electromagnetic radiation therapy to the eye or mucous membrane, powers as low as 50μWatts/cm² continuous or pulsed are found to be beneficial. Typically 10 mWatts/cm² are used on skin but this value is dependent on how fat or muscular the subject is and thus how deep the tissue/area/organ to be treated may lie beneath the skin surface. Typically radiation of the intensity 5 mWatts/cm² is used on mucous membranes.

Preferably when the electromagnetic radiation is pulsed it is applied for periods of at least 10-15 μseconds and more preferably is applied at a frequency/repetition rate in the range 480-800 Hz more preferably still the frequency/repetition rate is at, or about, 600 Hz.

Our studies have shown that the electromagnetic radiation can be either coherent or non-coherent the clinical outcomes are not affected by this parameter.

Preferably the electromagnetic radiation is applied to the affected area for at least 30 seconds and upto a few minutes. A typical exposure time for the skin or eye is in the region of 3 minutes, however for tissues well below the skin surface this time is increased according to the individuals fat/muscle layer depth and exposure could be up to 10 minutes.

It should be appreciated that the power source emitting the electromagnetic radiation will have to produce more than the required intensity for the clinical effect since we

have shown that approximately 99% of the applied therapeutic amount of light is lost across the skin surface during treatment. Thus the intensity of applied radiation will have to be corrected for when carrying out a treatment.

Our studies have shown that the first clinical effects can be detected following 30 seconds of treatment for herpetic infections and that the majority of immediate clinical effects are experienced following 90 seconds of treatment. However certain tissues are more sensitive, for example the mucous membranes are exposed to the dosing regimen for approximately 30 seconds and immediate clinical effects are noted after only 3 seconds of treatment.

From the foregoing it is understood that the electromagnetic radiation may be directed to the target site either continuously or in a switched (pulsed) manner. The main benefit of switching enables power conservation and facilities much higher peak power output, thereby improving clinical response.

Preferably, electromagnetic radiation therapy system also includes means for reducing the amount of ambient radiation which impinges on the site of infection. The presence of ultraviolet light and violet light as in sunlight exacerbates herpetic conditions and it is preferred to exclude wavelengths below 400nm. More preferably, wavelengths below 500nm are excluded.

Preferably the system further includes means for fixing the intensity of the radiation within a pre-determined range. The radiation output may be monitored with a visible display indicating correct function of the device both for intensity and wavelength.

Preferably the system further includes means for controlling the duration of the application of the radiation. Accordingly, the present invention is concerned with the use of electromagnetic radiation having a wavelength in the range from visible to infra red and applied at a low intensity such that no thermal damage is caused to any human or animal tissues.

In the case where the system is to be used in such a way that radiation will be caused to enter the eye, it is preferred that the power intensity does not exceed 100 mWatts/cm^2. Otherwise, the power intensity may be higher and can suitably be delivered in pulsed form, thereby obtaining several watts of momentary power output, allowing good penetration of tissue and substantial systemic effect.

The radiation producing means are preferably solid state light emitting devices, more preferably solid state light emitting diodes or gas discharge devices. The radiation from such devices can be electrically operated or the radiation can be delivered to an applicator via a fibre-optic delivery system.

Preferably, the radiation emitter includes a PN junction arranged to emit radiation with a wavelength centring at or about 1072nm or at or about 1268 nm. A single light diode assembly may include a plurality of orientated junctions.

Infrared emitting diodes may be arranged not only to emit radiation at a specific frequency but also to emit a high intensity divergent beam.

A gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072 nm.

Another preferred radiation producing means is a laser diode device, an example being a laser diode emitting light at a frequency of 1064.nm. Such a light emitting means is of low power intensity having a divergent beam and not giving rise to thermal damage. It may be used to treat many conditions, including pain relief.

The present invention also provides the use of divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm and an intensity of at least 50μWatts/cm^2 to treat an area of biological tissue of a living human or animal subject.

Preferably the electromagnetic radiation as produced by the system of the invention provides for treating conditions such as, without limitation, herpetic infections, bacterial and/or viral infections of the skin or upper respiratory tract, ophthalmic conditions such as "dry eye syndrome", caustic injuries, musculoskeletal conditions, inflammatory conditions such as rheumatoid arthritis and malignancies, reduction of scarring, promotion of wound healing, sports performance and providing acute and chronic pain relief.

The use of restricted bandwidth radiation can enhance the immune system as a result of which the body is able to combat infections, such as the herpes virus.

Although reference has been made to infections caused by the herpes virus, the present invention is not limited to such infections. It is applicable to other infections caused by all viruses including HIV, common cold and influenza viruses.

The present invention also provides a method of treating an area of biological tissue of a living human or animal subject comprising applying to said area divergent electromagnetic radiation having a wavelength of between 950 and 1500 nm at an intensity of at least 50μWatts/cm^2.

Preferably, the area to be treated is irradiated so that the affected tissue receives at least 50-500 μWatts/cm^2 peak power of radiant energy, depending on the tissue to be treated. A factor here is the period of irradiation and, preferably, the period should be at least a specified minimum of 10-15 μseconds at a repetition rate /frequency of 450-800 Hz and preferably for at least 30 seconds duration.

Brief Description of the Drawings

Embodiments of the invention will now be described, by way of examples only, and with reference to the accompanying drawings, in which: -

Figures 1 to 4 are a view with cover removed, side view, under view and front view respectively of a first embodiment in accordance with the present invention;

Figures 5 to 7 are a front view, top view and under view of a second embodiment in accordance with the present invention;

Figures 8 to 10 are a back view, top view and a side view of a third embodiment of the present invention;

Figures 11 and 12 are a side view and a view from the right (as seen in Figure 11) of a fourth embodiment in accordance with the present invention; and

Figures 13 and 14 show further embodiments of the present invention.

Detailed Description of Preferred Embodiments

Referring to Figures 1 to 4, a first embodiment in accordance with the present invention includes a hand held divergent narrow wavelength radiation source 4 with a built in timer and ambient radiation detector. A single wavelength is used at any one time, preferably in the infrared spectrum. However, the effective wavelengths, which may be covered by such a device, extend from the visible spectrum to the infrared. In another embodiment of the invention, two wavelengths are used, one that is visible and the other that is invisible, particularly in the case where the optimal wavelength is in the infrared.

Radiation source 4 includes an elongate, rectangular cross-section hollow body with one end 1 being transparent to light. The radiation source includes an array of light emitting diodes 2 mounted close to transparent end 1. Power is delivered to devices 2 by means of batteries 3 located within the body 4.

The radiation source is provided with two On/Off switches 5, which may be actuated to initiate the operation of the internal electronics. Both buttons 5 have to be pressed simultaneously in order to operate the device correctly, thereby preventing inadvertent use of the device. Close to the end opposite transparent end 1 is a utility

hole 6 which allows the radiation source to be hung up or attached to another article such as a bunch of keys.

The radiation source is provided with control electronics, which limit the time that the radiation source is on and then automatically switches off the radiation source. The control electronics monitor the ambient radiation and, in the event that the ambient radiation is of an intensity that would interfere with the therapeutic effect of the radiation source, an alarm buzzer (not shown) sounds. The radiation emitting devices 2 and their location and arrangement within the radiation source are such that the radiation emitted from the radiation source is in the form of a divergent light beam. Flange 8 restricts the ambient radiation incident on the area whilst being treated.

The radiation therapy system of the present invention could be adapted to be portable and for use by those individuals wishing to have their own self-contained and battery operated devices. Additionally it could be adapted so that during use an animal or human appendage could be located within a hollow body 3 to receive radiation emitted therefrom. This particular modification is particularly suited to treatment of genital herpes around the scrotal sac and/or penis.

Referring to Figures 5 to 7 of the accompanying drawings, a second embodiment in accordance with the present invention is in the form of a multi-panel narrow wavelength radiation source. In this case, a plurality of panels 3 are mounted in a side by side relationship on hinges 7 which, in turn, are connected to a stand 9 by means of arms 8 and 10. The arrangement is such that the panels can move relative to each other and the stand can be adjusted to alter the direction of illumination. The stand either extends from the floor or is attached to a chair or bed.

The front wall of each panel 3 is transparent and, mounted below the front wall, is an array of radiation emitting devices 4.

As with the earlier above described embodiments this embodiment of the invention includes control electronics to limit the time of the application of the radiation and to monitor the ambient radiation and provide an alarm when the threshold value of the ambient radiation is exceeded.

Referring to Figures 8 to 10 of the drawings, a third embodiment in accordance with the present invention is in the form of a narrow wavelength radiation source with adjustable headgear.

The radiation source is, in use, located on the operator's head and includes two panels 1, 5 of radiation emitting devices, panels 1 being separated by an intervening notch 1a. These radiation panels 1 can be used either simultaneously or separately, there being provided a switch (not shown) to direct electrical power to one or both of panels 1.

The radiation panels 1 are held close to the eyes by adjustable control elements 2.

The radiation source is provided with control electronics 4, which limit the time of application of the photons to the affected site and also automatically switch off the radiation at the end of the application period. As before the control electronics monitor the ambient radiation and provide an alarm when the threshold level is exceeded.

Referring to Figures 11 and 12 of the accompanying drawings, a fourth embodiment of the present invention is in the form of a narrow or restricted bandwidth radiation source for delivery of photons to an orifice. In this case the body of the radiation source includes an elongate cylindrical portion 2 having at one end a flange 4 whose shape is indicated in Figures 11 and 12. At its other end, elongate portion 2 is hemispherical. Radiation emitting devices are located both in the elongate portion 2 and the flange 4 and this radiation source can be used to deliver photons to any orifice in the human/animal body, for instance, the vagina, anus, oro and

nasopharynx and buccal cavity. The radiation source may be provided in different sizes according to the size of the orifice into which it is to be inserted.

Control electronics limit the time of irradiation and monitor the ambient radiation, as with the previously described embodiments of the invention.

Figures 13 and 14 illustrate devices useful in the treatment of the common cold and acne.

The common cold is caused by a viral infection of the upper respiratory tract. The viral particles are almost exclusively found in the pharynx, sinuses and nasal passages.

The device is a radiation emitting apparatus, which delivers a narrow bandwidth radiation, which, is of a wavelength, that will penetrate the superficial skin and penetrate the underlying tissue to sufficient extent to generate a therapeutic effect.

The device in Fig 14 is flexible and is placed against the patient's face whilst he is lying supine. Notch 1 provides an aperture for the patient's eyes. Panel 2 provides treatment for the frontal sinuses. Panel 3 provides treatment for the maxillary sinuses and nose, and the intervening bridge 1a provides treatment for ethmoid sinuses and nose.

The device in Fig 13 is a flexible radiation emitting apparatus, which is placed against the patient's neck so that the points 5 approximate the base of the patient's ears. This apparatus delivers radiation for therapeutic effect to the patients larynx, oropharynx and laryngopharynx. Depression 4 fits underneath the patient's chin.

Devices for treating acne are as shown in Figures 13 and 14 and comprise several panels of variable shape and size. All the panels have a radiation emitting surface 2 and are flexible to enable the panel to follow the contour of the face and neck. Panels

6 and 7 (Figure 13) are applied to the inferior aspect of the chin and the neck respectively.

Panels in the Figure 14 device are applied to the face so that notch 1 enables the patient to see whilst being treated. Bridge 1a treats the bridge of the nose and extension 3 the cheeks. Notch 4 rests on the tip of the nose allowing the patient to breathe comfortably during treatment. Panel 8 is used to treat the chin area and the area adjacent to the mouth.

Where the chest and/or back is involved a larger version of panel 6 would be used.

Due to the superficial nature of the pathology ambient radiation is of significance and an ambient radiation detector is utilised.

Treatment time is at most 10 minutes but typically 5 minutes.

It should be appreciated that two or more of the above-described devices can be used in conjunction with one another. An example is in the treatment of paediatric herpetic stomatitis where the device for delivery of radiation to an orifice could be used in conjunction with the multipanel device to ensure adequate delivery of the radiation system.

The application of radiation in the manner described appears to give the patient immediate (within 6 minutes) relief from any pain which is chemically mediated irrespective of the inflammatory condition causing it i.e. it gives pain relief in conditions other than those caused by viral infections. It does not affect the conduction of pain impulses as in local anaesthetics.

Experimental Results

Examples of the invention will now be described with reference to the treatment of particular conditions.

Herpes

The radiation-emitting surface was placed against the cold sore for at least 90 seconds, typically 4 minutes. The environmental conditions must be such that the ambient radiation to the cold sore must be decreased below acceptable levels. This can be achieved either by switching the radiation off or designing the device with a flange around the outside, diminishing the ultraviolet light to the area. Treatment is only once a day. One treatment may be all that is necessary however, in view of the fact that this also enhances wound regeneration and the wound regenerative effect only lasts 24 hours, daily treatments would improve clinical response. Various wavelengths were evaluated using a double blind control trial, Zovirax being given to the control patients. The average time for patient to be treated with 660 nm radiation took 7.5 days. The average time for a patient to be treated with 1072nm radiation was 3 days if lesion was already present. However it was less than 12 hours if the patient only has a tingling sensation.

99.5% of patients abort their attack if they are treated within the tingling period using 1072nm radiation. The cure rate of the patients receiving radiation treatment was total, in that none had a recurrence of their cold sores at the site treated. However 20% of the acyclovir treated group had recurrence at the site of treatment.

The number in the trial was 300.

A further study was conducted in a double blind protocol comparing radiation treatment to acyclovir. The group receiving radiation therapy had cold sores that healed within 4.7 days and the group receiving acyclovir had cold sores that healed within 4.7 days. Statistical analysis resulted in a p value of 0.027, which was statistically significant.

Please refer to the table below for further details.

Treatment	Number of Patients	Mean Time to Healing (days)
Placebo radiation plus acyclovir	14	6.9
Active radiation	15	4.7
Active radiation plus placebo cream	16	6.7
Acyclovir	18	8.5
Red Light	20	7.5

Genital herpes

Again the applicator was required to follow the contours of the genitals and for a woman the cervix and posterior fornix was treated simultaneously with vagina and perineum. The treatment period is only 4 minutes. Due to the shape of the device, ambient radiation is excluded from the treatment area, and darkened room is not necessary.

A total of eight patients have been treated, all of who have reported a shorter duration of their recurrent attacks of genital herpes. In addition, after one year of treatment, for each attack, all patients have been free from recurrence for the last 6 months, whereas they typically had an attack per month.

Shingles

The radiation panel was applied to the area that is infected, for periods of 4 minutes. If the panel is applied to the actual skin surface and the panel is optically opaque it will occlude the ambient radiation from the area and hence allow treatment to proceed successfully. The only exception where a darkened room is essential is for the treatment of ophthalmic conditions when one cannot have the radiation-emitting surface close to the eye because of the generation of heat. The generation of heat in association with ophthalmic conditions is contraindicated. A helmet was used with an ambient radiation detector with alarm so that the radiation can be delivered to the

orbital region. Again the treatment period was 4 minutes. Generally ophthalmic conditions are treated on a daily basis. However, ophthalmic herpes can be treated once every three days to achieve a positive result.

Four patients have been treated; all of who had significantly shortened healing periods and decreased incidence or recurrence.

The common cold

The patient was reclined on a bed, preferably in subdued lighting, but this is not essential. The device was placed against the skin ensuring that the frontal, ethmoidal and maxillary sinuses are covered. Another panel was placed again the neck, ensuring that the device goes as high as the angle of the jaw to enable treatment of the pharynx and larynx areas. The treatment cycle is at least 4 minutes. After that has been completed an oral device was used which is very similar to the vaginal applicator without the flange. The device was inserted into the patient's mouth. The treatment period was again for 4 minutes. This applicator has a disposable outer skin, which is changed with each patient. The applicator will treat the soft palate and the back of the oral pharynx and the top of the nasopharynx where the surface applicator would not achieve acceptable penetration levels. Using this protocol alleviation of the pain associated with pharyngitis was achieved immediately, i.e. within 90 seconds, and the symptoms associated with oral pharyngitis have been alleviated within six hours.

Ten patients have been treated. Of note is that unrestricted light can be applied to the pharynx with immediate relief of symptoms, however for improved efficacy, light of the wavelength 1072nm is required to be applied to the face and sinuses. We noted that in all cases the sore throat was improved immediately and symptoms of congestion and flu-like illness were alleviated in 4-6 hours.

Acne

Using the same applicator adolescent acne can be treated by the simple addition of a chin extension. The treatment time is 4 minutes. Ambient light is important but not in as much as the applicator will have an opaque surface so therefore it will be sheer proximity to the skin reduce ambient light to the skin. Applications should initially be every two to three days and maintenance would be perhaps once a week.

Twelve patients have successfully been treated with light of the light therapy system. Results indicate that if 950nm 5mm diodes were used there was a marked exacerbation of the disease process, however when using 950nm 8mm diodes there was a slight increase in inflammation but an overall improvement. The use of restricted radiation resulted in a rapid resolution of acne over 7 days. Daily treatment enhanced clinical results. Once a clinical result was achieved, the regimen was maintained for 1-2 treatments per week for a satisfactory outcome.

Musculoskeletal disorders

Treatment of musculoskeletal disorders such as tennis elbow gout, muscle injuries and knee injuries. The application time again is only 4 minutes. The radiation is directed over the affected area and gentle pressure is applied. Once the treatment is complete the patient feels immediate pain relief and improved joint movement. Muscle stiffness is greatly improved. This is a distinct advantage in the treatment of gout since this can be an extremely painful condition. The treatment could be repeated after 24 hours. Generally speaking treating prior the 24 hours is not indicated, as there is no additional clinical benefit.

Post-operative wounds

24 hours after an operation, a 4-minute treatment period reduces pain for 6-8 hours and this was repeated three to four times a day to enhance would healing. The treatment may be used on a daily basis with or without the pain for post-operative wounds.

Seven volunteers. all of whom had minor surgery found decreased scar formation if the area of surgical incision was treated daily for 10 days commencing on the day of surgery. Thus it is envisaged that the present invention has applications in the treatment of keloids, burns and cosmetic surgery.

Connective Tissue Diseases

Rheumatoid arthritis is an example of this group of conditions. The painful areas are treated in a device which comprises one fixed panel in which the hands are placed on and a flexi panel which is placed over the top of the hands applying gentle pressure to aid additional penetration of the skin. The treatment time is 4 minutes. Ambient radiation does not appear to be a significant factor in the treatment of rheumatoid arthritis. Part of the treatment protocol can also be in the treatment of thymus, liver and regional lymph nodes, which are all associated with antigen recognition. Again treatment time is 4 minutes. The thymus, lymph nodes, liver and spleen may be treated once a week, whereas the hands may be treated initially once a week. However, during an acute exacerbation they can be treated daily. If treated more than once daily there appears to be no advantage.

A small trial involving eight patients in the Rheumatology Clinic resulted in the findings that those receiving placebo radiation treatment felt more relief than those patients receiving active 950nm radiation. However, when using radiation in the restricted wavelength according to the present invention, all ten patients reported a clinical benefit compared to the placebo treatment. In addition we found that if the thymus and other aspects of the reticuloendothelial system were treated with the restricted radiation the patients experienced an overall cessation of their arthralgia and myalgia.

Malignancy

The area of the tumour is treated together with treatment to the antigen recognition centres such as thymus, spleen, liver and lymph nodes. Daily whole body treatments may be carried out.

Bacterial Infections

A number of diverse minor bacterial infections have been treated successfully in 35 patients. In all cases the infection had been present for at least three days and was considered to be worsening daily. At the time of treatment each patient would have ordinarily been prescribed an oral antibiotic. In 70% of cases the infection was resolving 6 hours after treatment and was completely better within one day. In the remaining 30% of cases the infection had improved considerably within one day and following a second radiation treatment, the infection was gone by the second day. Of clinical note was the observation that in the Caucasians treated there was a significant decrease in superficial scar tissue at the site of assault. As previously noted, the 8mm 950nm diode unrestricted radiation source was effective but not as effective as the restricted radiation of 1072nm of the present invention.

Sports Medicine

Treating all muscle groups prior to training will increase the level to which the athlete can train by as much as 50%, in addition to decreasing the incidence of muscle injury.

In a double blind trial, five volunteers were used by treating one limb with placebo radiation and the corresponding other limb with active radiation. In all cases the volunteers were able to increase their effort tolerance before feeling muscle fatigue by 30-50% in the limb treated with the active radiation.

Muscle injuries have been successfully treated in 35 patients. The pathology involved included rotor cuff syndrome, tennis elbow, lower back pain and lumbar fascitis. The response to therapy ranged from immediate relief in 30% of cases to complete relief after 24 hours in the remaining 70%. Daily treatment is required until the problem is resolved.

Ophthalmic Conditions

Chronic ophthalmic pain was successfully alleviated permanently in 90% of the eleven patients treated.

Unstable corneal epithelium (over a period of 6 weeks) which resulted in recurrent corneal ulceration, was stabilised in 6 patients promoting an intact corneal surface within 5 days of commencement of daily treatments of radiation therapy.

Four patients with conjunctivitis sicca or dry eye syndrome, reported significantly decreased eye irritation and produced significantly less debris accumulation within fornices following radiation treatment. Of note was the experience that whilst radiation centred on 1072nm was effective in this condition, radiation centred on 1268nm was more effective. Once weekly treatment with radiation was sufficient to alleviate symptoms.

Episcleritis and other inflammatory conditions of the eye were successfully treated in 11 patients. Daily treatments were necessary to obtain the desired clinical effect. The recurrence of the inflammatory condition was decreased in all cases. All patients treated had suffered their conditions over several months and resolution occurred in 3-4 days without the use of eye drops.

Severe caustic injury to the eye is considered untreatable and almost always results in destruction of the cornea and blindness. Animal experiments (conducted in South Africa) have indicated that caustic injury is treatable with the radiation of the present invention.

Five pairs of rabbit eyes were exposed to a supersaturated solution of NaOH for 30 seconds after topical administration of an anaesthetic. All eyes were washed out thoroughly following the caustic injury and it was noted that the corneas were immediately opaque following the injury. One eye of each rabbit was then either treated with conventional steroids plus antibiotic whilst the other eye was treated

with the radiation of the present invention. All rabbits were sacrificed 4 weeks following twice daily treatment. In all cases the eyes that had been treated with conventional therapy (steroids plus antibiotic) rapidly developed panophthalmilitis with resulting blindness, whilst the eyes treated with the radiation therapy of the invention showed that the anterior chamber, lens, vitreous and retina were intact despite corneal damage. In addition the scar tissue in the radiation treated eyes was reduced by at least 50% compared to the conventionally treated eyes.

Further experiments involving a less concentrated solution of NaOH being applied for a longer duration, 3 minutes, resulted in corneal damage to all eyes as gauged by pale milky appearance to the corneas. The same protocol of treatment was applied, I.E. one eye being treated in conventional manner and the other by radiation therapy. The animal were sacrificed following two weeks of treatment and the results showed that eyes treated with the radiation therapy were clear whilst the conventionally treated eyes remained opaque.

The ability to reduce scarring was investigated using 5 pairs of rabbit eyes. Each eye was scarred by a 4mm linear full thickness incision in the centre of the corneas under topical anaesthesia. One eye was treated conventionally and the other by radiation therapy. All eyes healed however the eyes receiving radiation therapy healed at a faster rate with scarring reduced by 50%. It was noted that radiation centred on 1072nm gave best similar results.

Pain

Radiation at 950 nm was only marginally effective compared to the restricted radiation at 1072 and 1268 nm. It was noted that 1072 nm was more effective than 1268 nm radiation in treatment of acute pain as caused by a superficial burn However, 1268 nm radiation was reported as more effective at alleviating deep muscle pain caused by muscle injury.

Pain was gauged in patients by subjective assessment.

Thus it will be appreciated that the radiation therapy system of the present invention has wide application in treating a variety of different diseases and conditions. The radiation therapy system effects on a patient are rapidly felt and since the system is non-invasive it presents a less stressful/traumatic therapy to the patient. Moreover, the system could be used to treat a wide variety of patients quickly thus reducing the financial burden to the health service.

AMENDED CLAIMS

1. An electromagnetic radiation therapy system comprising means for emitting divergent electromagnetic radiation between 980 nm and 1500 nm and being capable of producing, at the site being treated, a radiation intensity of at least 50 μWatts/cm^2 and up to 2 Watts/cm^2.

2. An electromagnetic radiation therapy system according to either of Claims 1 or 2 wherein the wavelength is in the range 980nm-1300nm.

3. An electromagnetic radiation therapy system according to any preceding claim wherein the wavelength is at, or about, 1072nm.

4. An electromagnetic radiation therapy system according to any preceding claim wherein the wavelength is at, or about, 1268nm.

5. An electromagnetic radiation therapy system according to any preceding claim wherein the half angle divergence of the electromagnetic radiation is in the range 15° to 45°.

6. An electromagnetic radiation therapy system according to any preceding claim wherein the electromagnetic radiation is continuous or pulsed.

7. An electromagnetic radiation therapy system according to any preceding claim wherein, in the instance of the electromagnetic radiation being continuous, the intensity is at least 50 μWatts/cm^2 for treatment of eyes and mucous membranes and up to 2 Watts/cm^2.

8. . An electromagnetic radiation therapy system according to any preceding claim wherein, in the instance of the electromagnetic radiation being continuous, the intensity is at least 500 μWatts/cm^2 for treatment of skin and up to 2 Watts/cm^2.

9. An electromagnetic radiation therapy system according to any of Claims 1-6, wherein in the instance of the electromagnetic radiation being pulsed, the intensity is at least 50 μWatts/cm^2 peak power for treatment of eyes and mucous membranes and the average power is up to 2 Watts/cm^2.

10. An electromagnetic radiation therapy system according to any of Claims 1-6, wherein in the instance of the electromagnetic radiation being pulsed, the intensity is at least 500 μWatts/cm^2 peak power for treatment of skin and the average power is up to 2 Watts/cm^2.

11. An electromagnetic radiation therapy system according to any of Claims 1-6 or 9 or 10 wherein the average power of the pulsed electromagnetic radiation intensity is in the region of 50-100μWatts/ cm^2.

12. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-11 wherein pulsed electromagnetic radiation is applied for periods of at least 10-15 μseconds.

13. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-12 wherein the pulsed electromagnetic radiation is applied at a frequency/repetition rate in the range 480-800 Hz.

14. An electromagnetic radiation therapy system according to Claim 13 wherein the frequency/repetition rate is at, or about, 600 Hz.

15. An electromagnetic radiation therapy system according to any of Claims 1-7 or 9-14 wherein the pulsed electromagnetic radiation is applied to the affected area for at least 30 seconds and up to 15 minutes.

16. An electromagnetic radiation therapy system according to any preceding claim wherein the electromagnetic radiation therapy system also includes means for

reducing the amount of ambient radiation which impinges on the site of treatment.

17. An electromagnetic radiation therapy system according to Claim 16 wherein the means for excluding ambient radiation excludes radiation below 400-500 nm.

18. An electromagnetic radiation therapy system according to any preceding claim further including means for fixing the intensity of the radiation within a pre-determined range.

19. An electromagnetic radiation therapy system according to any preceding claim wherein radiation output is monitored with a visible display indicating correct function of the device both for intensity and wavelength.

20. An electromagnetic radiation therapy system according to any preceding claim further including further including means for controlling the duration of the application of the radiation.

21. An electromagnetic radiation therapy system according to any preceding claim wherein the radiation producing means are solid state light emitting devices,

22. An electromagnetic radiation therapy system according to Claim 21 wherein the solid state light emitting devices are solid state light emitting diodes or gas discharge devices or a laser diode device.

23. An electromagnetic radiation therapy system according to either Claim 21 or 22 wherein radiation from such devices is electrically operated or delivered to an applicator via a fibre-optic delivery system.

24. An electromagnetic radiation therapy system according to any of Claims 21-23 wherein the radiation emitter includes a PN junction arranged to emit radiation with a wavelength centring at, or about, 1072nm or at, or about, 1268 nm.

25. An electromagnetic radiation therapy system according to Claims 24 wherein a single light diode assembly include a plurality of orientated junctions.

26. An electromagnetic radiation therapy system according to Claims 22 wherein the gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072 nm or 1268 nm.

27. Divergent electromagnetic radiation having a wavelength of between 980 and 1500 nm and an intensity of at least 50μWatts/cm^2 and up to 2 Watts/cm^2 for use in treating an area of biological tissue of a living human or animal subject.

28. Divergent electromagnetic radiation according to Claim 27 for treating herpetic infections, bacterial and/or viral infections of the skin or upper respiratory tract, ophthalmic conditions such as "dry eye syndrome", caustic injuries, musculoskeletal conditions, inflammatory conditions such as rheumatoid arthritis and malignancies, reduction of scarring, promotion of wound healing, improving sports performance and providing acute and chronic pain relief.

29. Divergent electromagnetic radiation according to Claim 27 for use in treating the immune system as a result of which a human or animal subject is able to combat infections, such as the herpes virus.

30. A method of treating an area of biological tissue of a living human or animal subject comprising applying to said area divergent electromagnetic radiation having a wavelength of between 980 and 1500 nm at an intensity of at least 50μWatts/cm^2 and up to 2 Watts/cm^2.

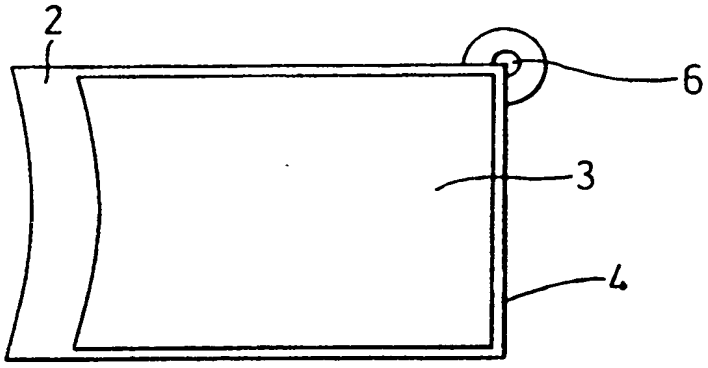


Fig. 1

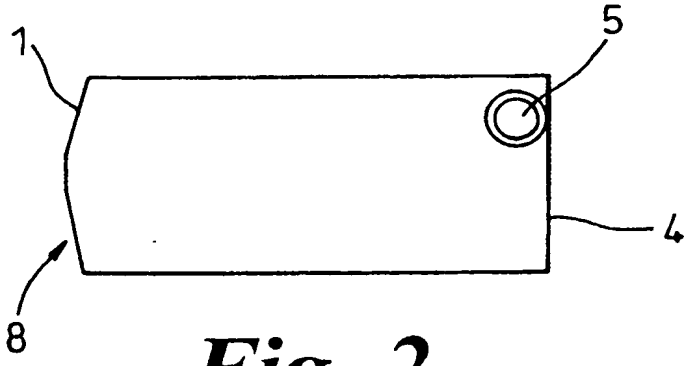


Fig. 2

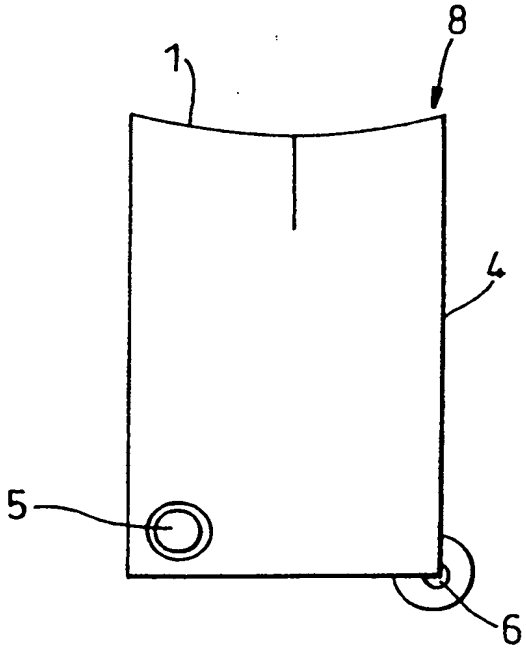


Fig. 3

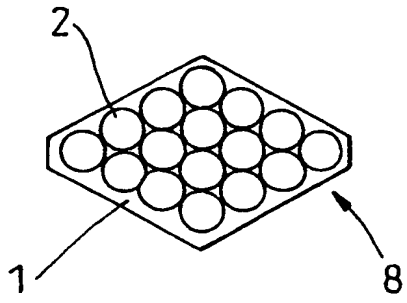


Fig. 4

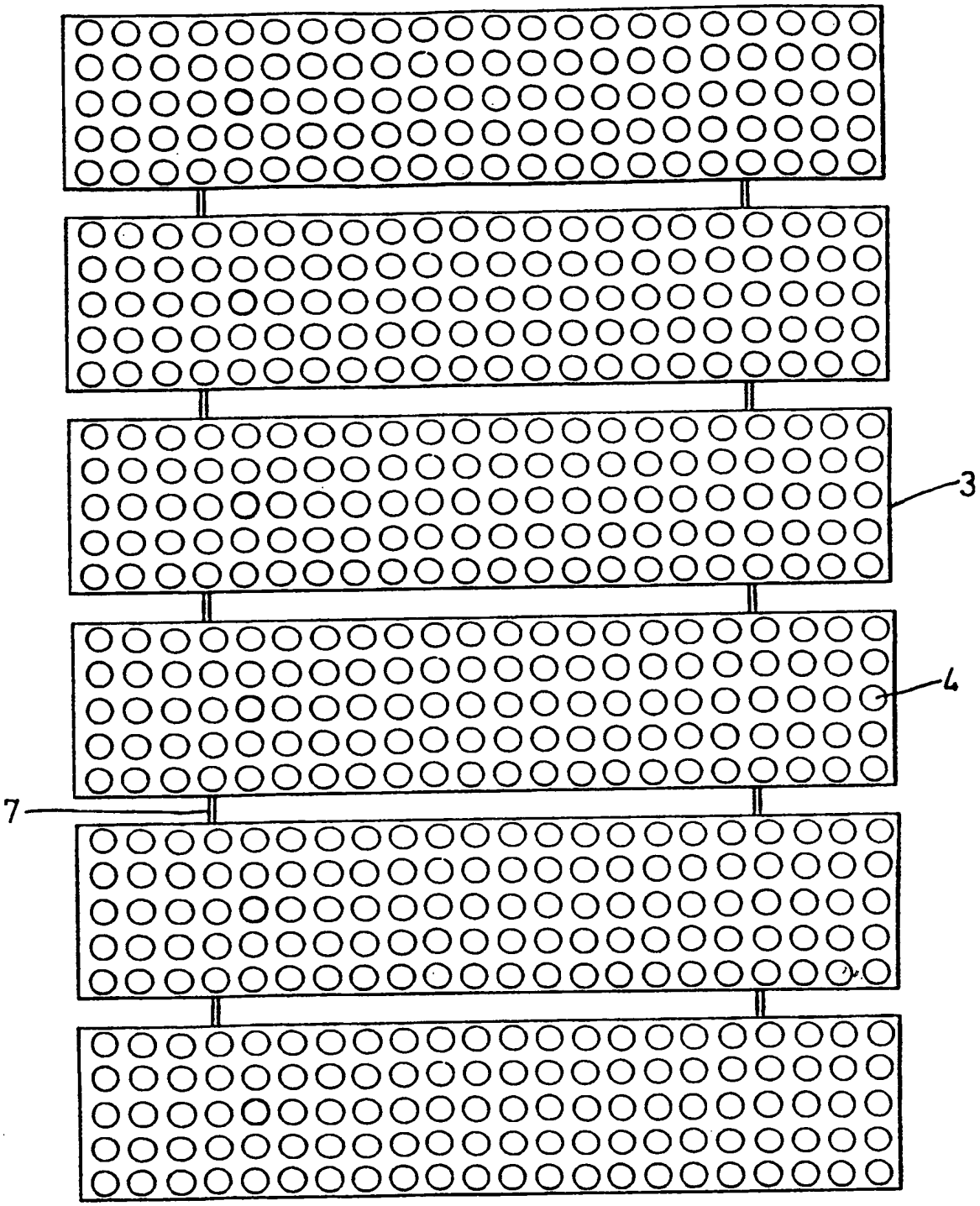


Fig. 5

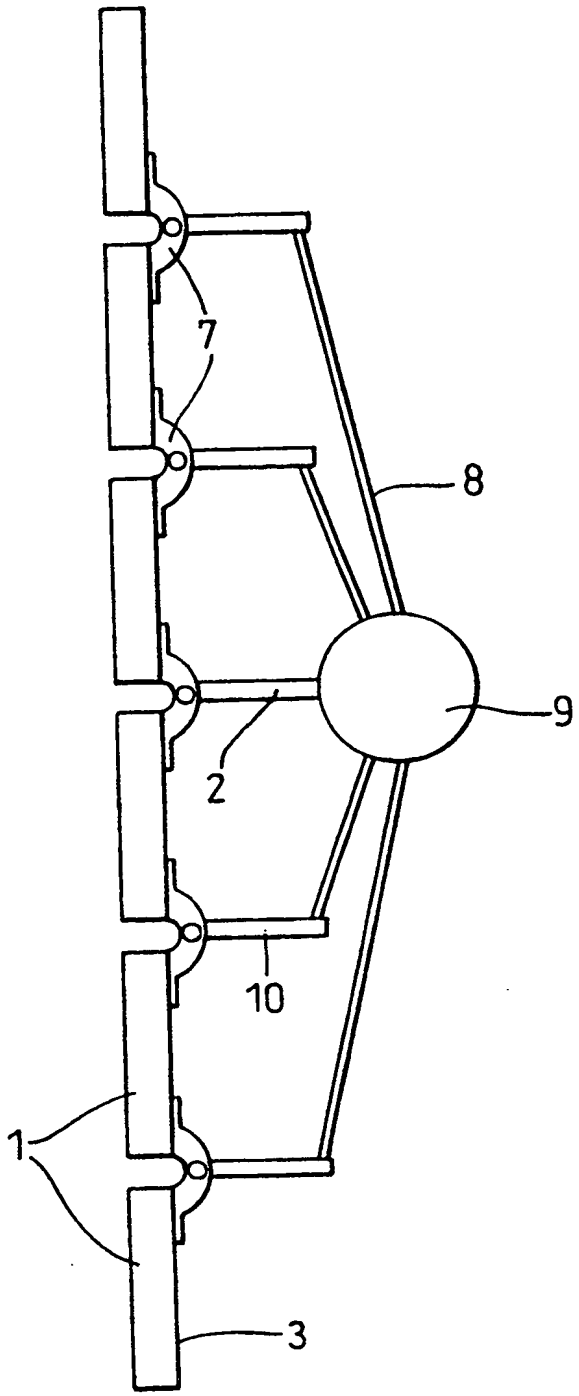


Fig. 6

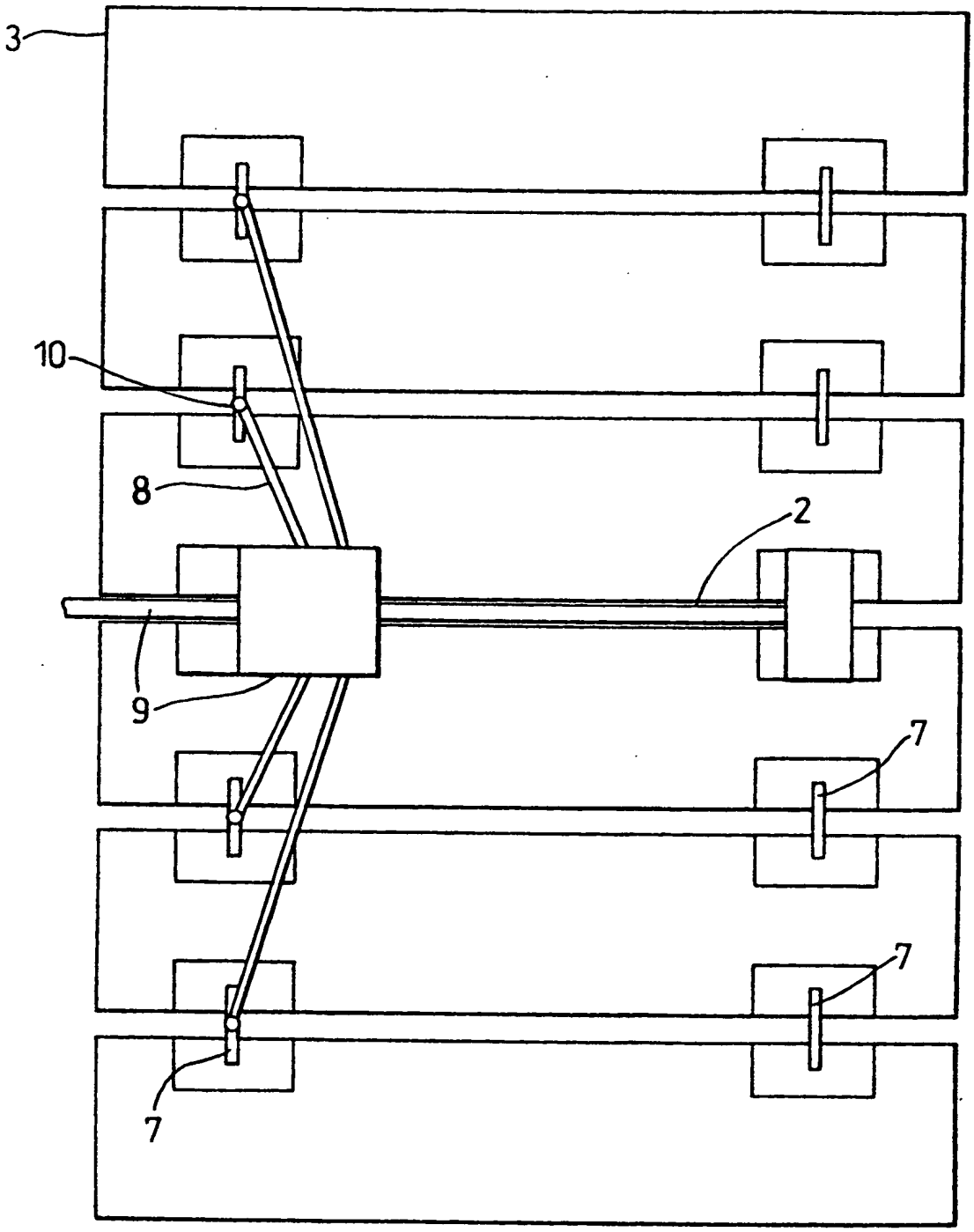


Fig. 7

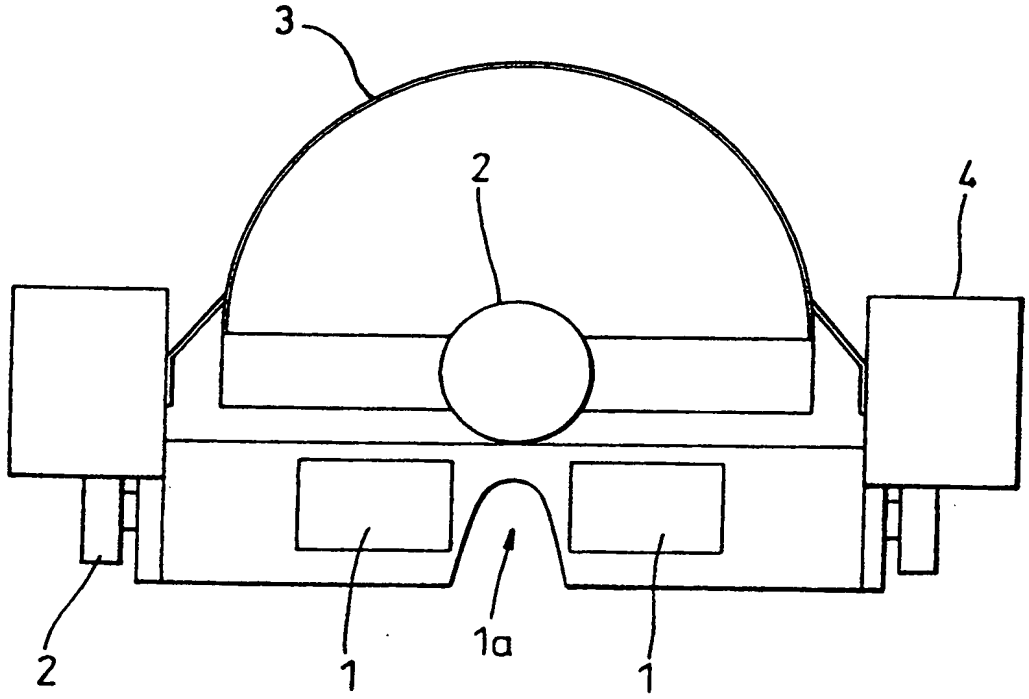


Fig. 8

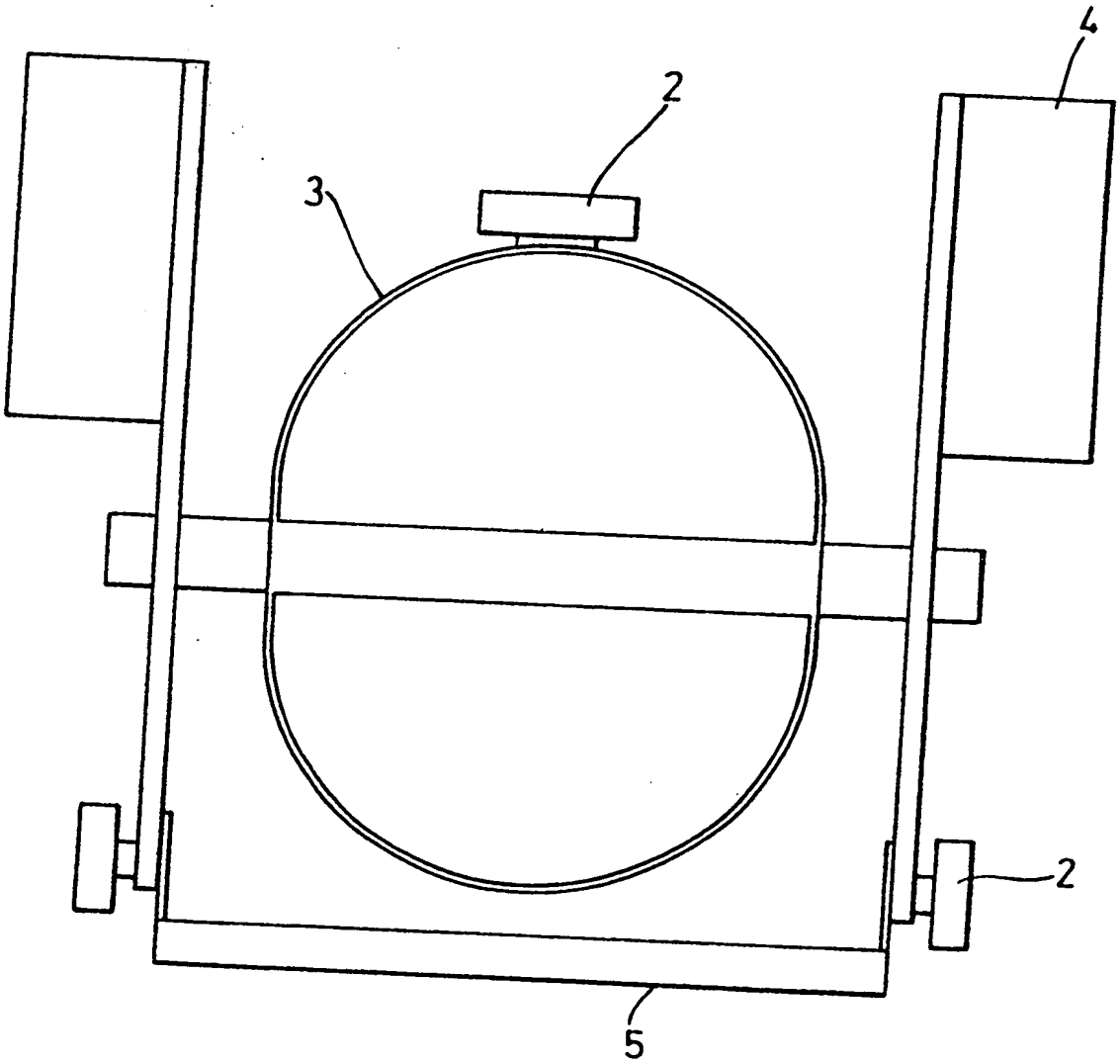


Fig. 9

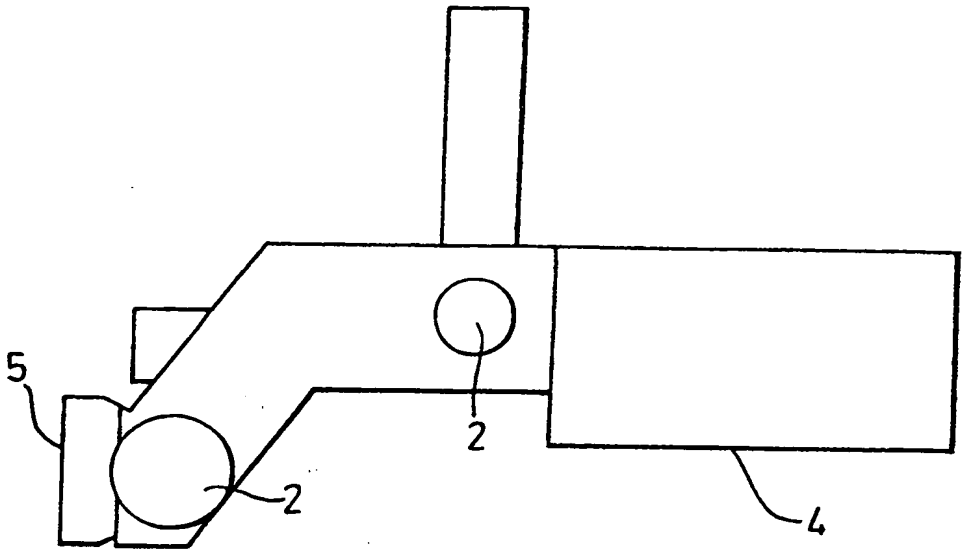


Fig. 10

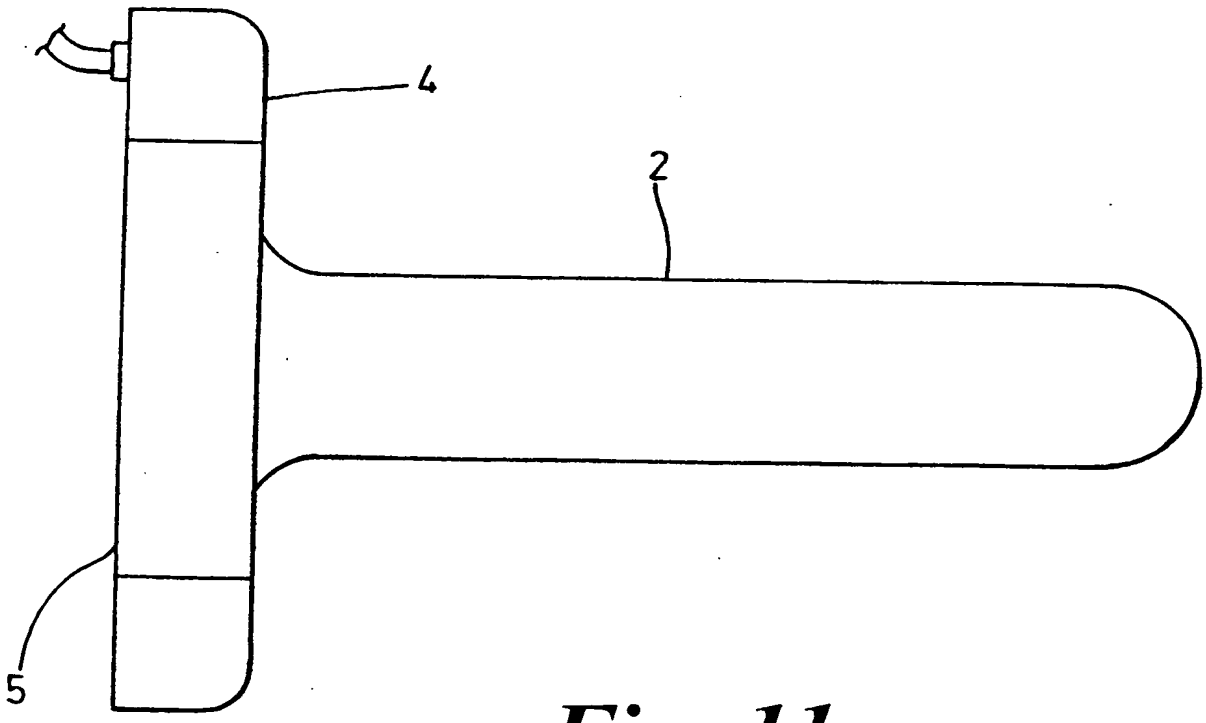


Fig. 11

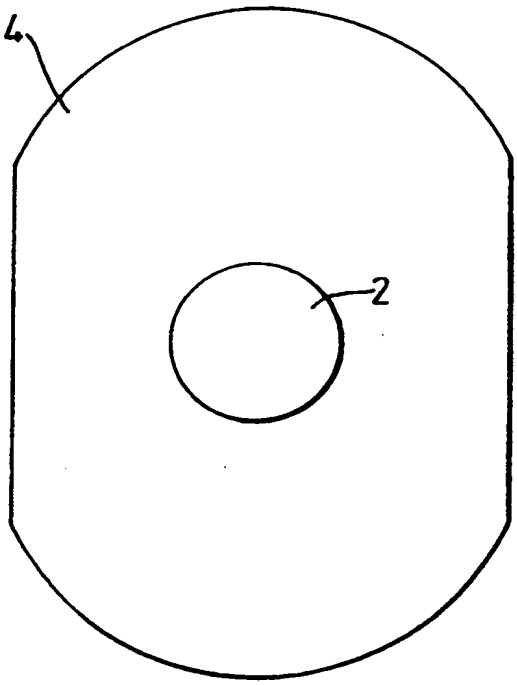


Fig. 12

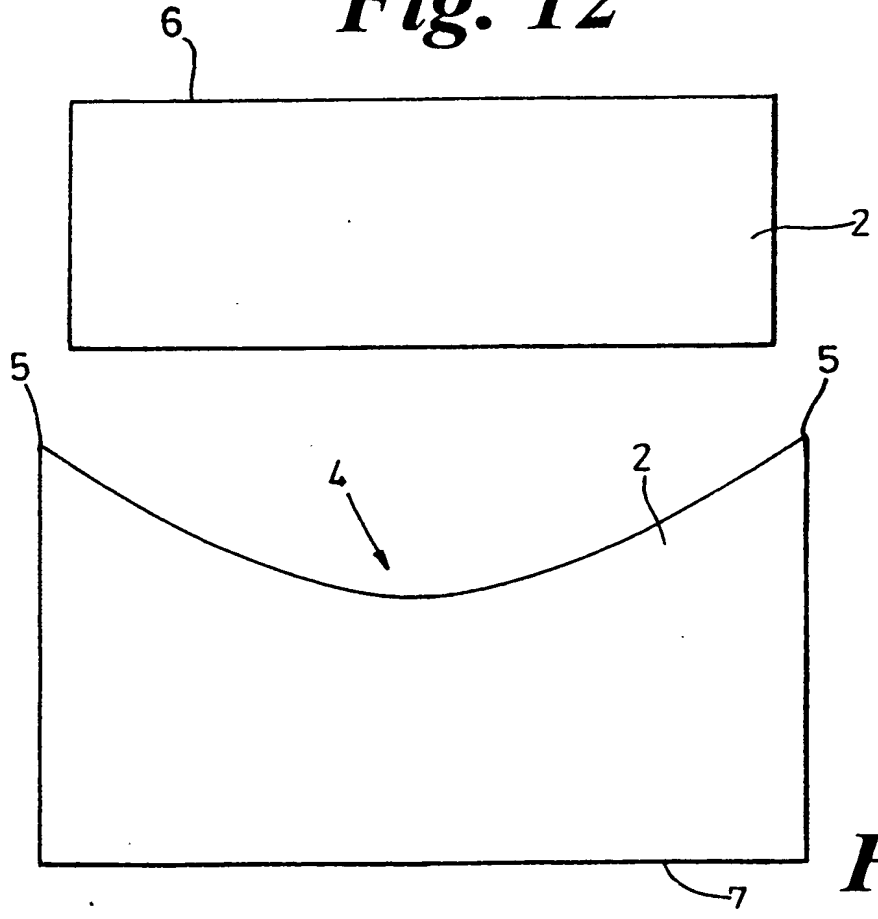


Fig. 13

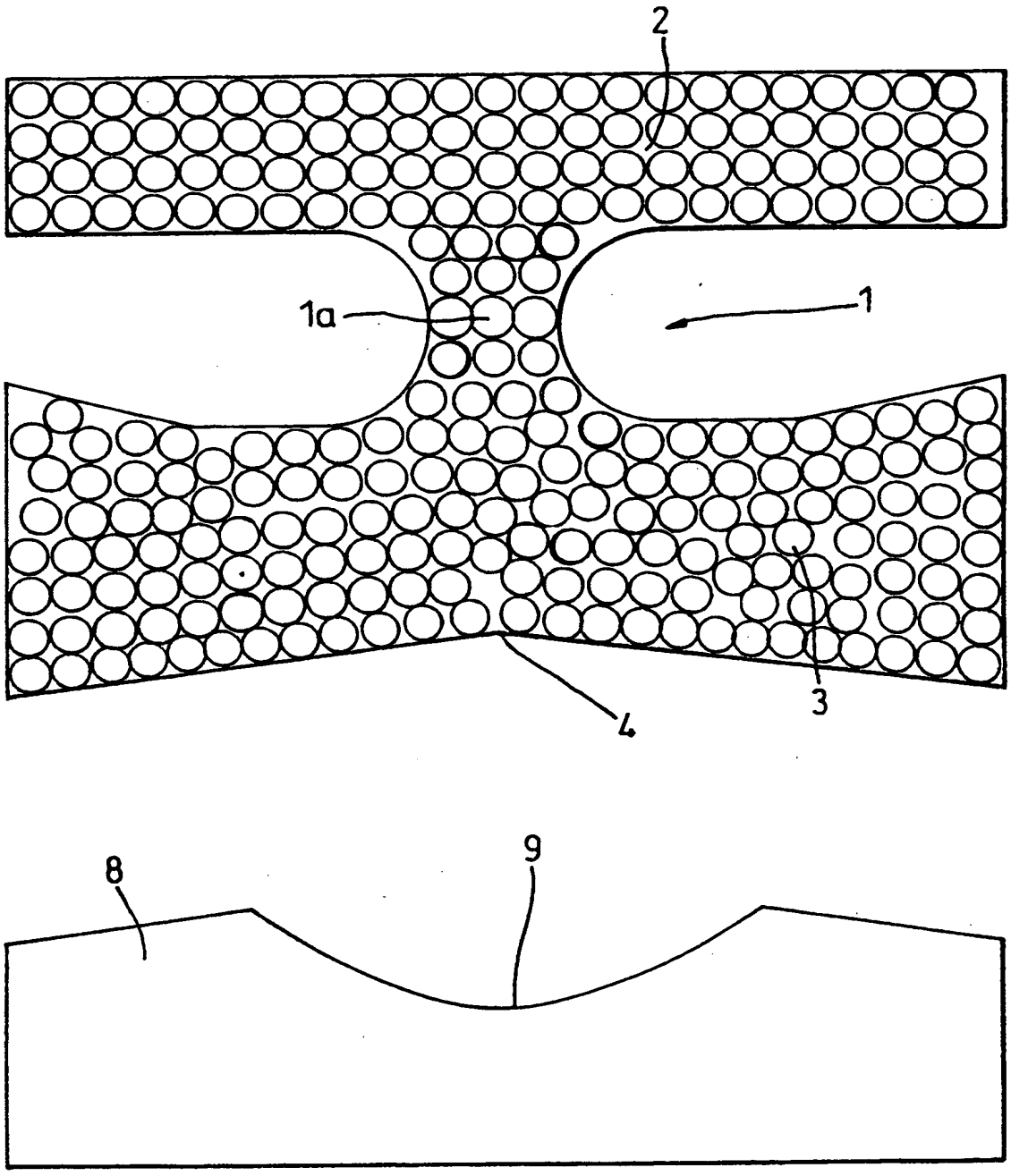


Fig. 14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 98/03073

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 464 436 A (SMITH) 7 November 1995 see column 4, line 37 - line 55; claim 6	1
A	US 5 500 009 A (MENDES) 19 March 1996 cited in the application see column 1, line 40 - line 55	1
A	EP 0 533 585 A (ZHOU) 24 March 1993 see page 18, line 11 - line 16 see page 6, line 5 - line 28	1
A	US 5 259 380 A (MENDES) 9 November 1993 cited in the application see column 5, line 50 - line 63	1
A	US 5 445 146 A (BELLINGER) 29 August 1995 cited in the application see abstract	1,3

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 January 1999	25/01/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Taccoen, J-F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

[redacted]ation on patent family members

[redacted]ational Application No
[redacted]T/GB 98/03073

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5464436 A	07-11-1995	AU 2464195 A	29-11-1995
		WO 9529736 A	09-11-1995
US 5500009 A	19-03-1996	US 5259380 A	09-11-1993
		CA 2120457 A	28-03-1995
		US 5549660 A	27-08-1996
EP 0533585 A	24-03-1993	CN 1070580 A	07-04-1993
		JP 6339537 A	13-12-1994
US 5259380 A	09-11-1993	US 5500009 A	19-03-1996
		US 5549660 A	27-08-1996
US 5445146 A	29-08-1995	WO 9630083 A	03-10-1996
		AU 695487 B	13-08-1998
		AU 2202395 A	16-10-1996
		BG 101938 A	30-04-1998
		BR 9510560 A	21-07-1998
		EP 0828534 A	18-03-1998
		FI 973827 A	29-09-1997
		NO 974497 A	24-11-1997
		PL 322464 A	02-02-1998
		SK 128397 A	08-04-1998